

The Philosophy for Investing in Urology: 5 Key Regulatory Risks

In the wave of physician practice management transactions, urology is poised to be one of the next hot sectors. In addition to the issues to consider in connection with any [physician practice transaction](#), below we discuss **five key regulatory risks to consider when investing in a urology practice**.

1. IMRT and Utilization Rates

Intensity-modulated radiation therapy (IMRT) is a common treatment for cancer, including prostate cancer. Several studies have documented that urologists with an ownership stake in the IMRT are more likely to treat patients with IMRT than urologists without ownership. These studies have led to additional focus on all financial relationships with the urologists, necessitating thorough diligence to ensure compliance with the federal Stark Law and state self-referral laws. When evaluating urology practices, it is important to closely review and analyze the financial relationships between the referring urologist and the entity providing IMRT services, whether that be the practice itself or a third-party radiation therapy provider.

2. Other Financial Relationships

As a referral source to various healthcare facilities and a specialist practitioner that receives referrals from other practitioners, diligence should include close examination of any financial relationship between them to ensure those relationships are structured to comply with applicable fraud and abuse laws. In addition, increased regulatory attention has been placed on physician relationships with industry vendors, including pharmaceutical and medical device manufacturers. It will be important to identify and vet any such relationships, even if the practice itself is not involved, because of secondary impact to an investment if any of the practitioners are implicated in a noncompliant relationship.

3. Medical Necessity

As recent False Claim Act lawsuits demonstrate, medical necessity is not sheltered as being within the realm of professional medical judgment. A number of recent lawsuits focused on lack of medical necessity as the primary basis for a claim being false. In part due to the findings referenced above regarding potential overutilization of IMRT, it is important to ensure that the medical necessity for these services is well documented; in particular, because there are other, less expensive treatment options. Moreover, with increasing program integrity efforts from both commercial and government programs, documentation that supports medical necessity for all services - not just IMRT - is critical to being able to respond to audit requests and retain collections for services billed. Support of medical necessity for services and treatment is also an important issue in a value-based care system.

4. Billing and Coding

Today, incorrect billing to federal healthcare programs, whether intentional or not, potentially creates an obligation to promptly repay. Moreover, as payment mechanisms evolve it is becoming more complicated to bill for urology services – to ensure services within a bundled payment are not separately billed and navigate the rules of numerous different payors. As a result, it is incredibly important to evaluate the integrity of medical records and billing and coding before investing in a urology practice. That evaluation should include a representative sample of claims, including high-risk ancillary services, even if the revenue for these ancillary services is proportionally small. Investors should engage with an expert on how to properly code for urology, IMRT and other ancillary services to evaluate the sample and verify that there have not been any overpayments. Key issues to examine include the following: documentation; sudden changes in practice patterns (utilization rates); physician extenders (up-to-date credentials and proper scope of practice for midlevels); and upcoding (and undercoding).

5. ASCs

Urologists perform many procedures in ambulatory surgery centers (ASCs) and may use an ASC as an extension of their practices. They also may have ownership in an ASC, either individually or through their group practice or another entity. ASCs increase the attractiveness of investing in urology groups because of the efficiency of the ASC model and potential profitability. Because urologists are referral sources to the ASC, their relationships with ASCs fall within the purview of the federal Anti-Kickback Statute and similar state laws. As a result, any ASC relationships should be carefully considered to ensure the relationships fall within a safe harbor or otherwise present low risk.

About Bass, Berry & Sims' Healthcare Private Equity Practice

Although there are issues to consider when investing in any physician practice, an investment in certain specialties such as urology present unique regulatory risks. With over 200 attorneys in its nationally recognized healthcare industry practice, Bass, Berry & Sims represents clients in more than 30 healthcare industry sectors. We regularly assist private equity firms and healthcare portfolio companies in finding creative and pragmatic, business-oriented solutions while navigating the unique healthcare regulatory, M&A and business environment.

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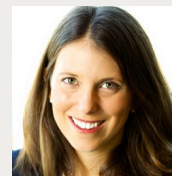
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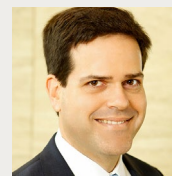
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